



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
INTER/INTRA-AGENCY AGREEMENT (IAA)
Payable Agreements (CDC is Procuring Agency)



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CDC IAA #: 00FED05404-03

13. ADMINISTRATIVE BILLING REQUIREMENTS: CDC's ALC is **75090421**. Other Agency's ALC: (required) 4610000010

Billing is to be made through the use of the Online Payment and Collection (OPAC) system. Please include CDC's Official IAA # from Block #1 on all OPAC billings and correspondence. When CDC provides funds to the performing agency, in advance of receiving the goods or services, the performing agency agrees to provide, within 15 days of the end of each quarter, statements of obligations and expenditures made during the quarter. The statements shall be provided to the following address: DHHS, CDC, FMO, AP, Attn: ADVANCES/OPAC Desk, MS D-06, 1600 Clifton Road, Atlanta, GA 30333. (If required by other agency, CDC's Tax Identification # is 586051157.)

14. ADDITIONAL BILLING REQUIREMENTS: *(This block must be completed if procuring services under the Economy Act.)*

- ☒ All funds provided by CDC under this agreement must be obligated by the performing agency by the end of the FY in which the funds expire. Any unobligated but expired funds may not be used to fund services in subsequent periods. The CDC Financial Management Office (FMO) must be notified of any unobligated funds pertaining to this agreement at least 15 days before the end of the FY so that the agreement may be modified to reduce the funding amount when appropriate. This notification shall be provided to the following address:
DHHS, CDC, FMO, AP, Attn: OPAC Desk, MS D-06, 1600 Clifton Road, Atlanta, GA 30333.

15. PARTICIPATING AGENCY FUNDING and/or INFORMATION:

(Please include name, telephone number, and email address of contact person.)

Name:	Telephone #:	Email:
Donna Hutton	(301) 504-0444	DHutton@cpsc.gov

16. ☐ The participating agency as a signatory to the Common Rule states that in accepting these Interagency Agreement funds, it will abide by the human subjects research requirements stated in the Common Rule, and certify that all necessary assurances and institutional review board (IRB) approvals are obtained.
- ☐ The participating agency is NOT a signatory to the Common Rule. Upon issuance of these Interagency Agreement funds, it is the responsibility of the CDC Center, Institute, or Office (CIO) to certify that all necessary assurances and institutional review board (IRB) approvals are obtained. The CIO Associate Director for Science (ADS) must determine the Applicability of Human Subjects Regulations.

17. OTHER REQUIREMENTS:

- A. Travel under this agreement is subject to allowances authorized in accordance with Federal Travel Regulations, Joint Federal Travel Regulations, and/or Foreign Service Regulations.
- B. CDC will retain the title to any equipment procured under this agreement, unless otherwise justified in the statement of work.

18. CDC ACCEPTANCE: *(please print)*

Name: Sue Binder, M.D.
Title: Director, NCIPC, CDC
Email address: SBinder@cdc.gov

Signature: *[Signature of Sue Binder]* Date: 5/20/02

19. PARTICIPATING AGENCY ACCEPTANCE: *(please print)*

Name: Donna Hutton
Title: Contracting Officer
Email address: dhutton@cpsc.gov

Signature: *[Signature of Donna Hutton]* Date: 6/11/02

This agreement may be terminated by either agency upon a 30-day advance written notice. This agreement may be modified by mutual written consent of all parties.

CDC
CENTERS FOR DISEASE CONTROL
AND PREVENTION

CDC 0. 1270 (E), CDC LAA Short Form #21, Rev. 5/2000, CDC Adobe Acrobat 4.0 Electronic Version, 2/2001

**INTERAGENCY AGREEMENT BETWEEN
THE CONSUMER PRODUCT SAFETY COMMISSION (CPSC)
AND
THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
(00FED05404-03)**

This document sets forth the terms of agreement for services, supplies, and/or material between the U.S. Consumer Product Safety Commission (CPSC) and the Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC).

This document serves as an addendum to the Interagency Agreement (number 00FED05404) between the Centers for Disease Control and Prevention and the U.S. Consumer Product Safety Commission covering the expansion of the National Electronic Injury Surveillance System (NEISS) to collect data on all injuries. This addendum covers a special study entitled: "**Adverse Events due to Therapeutic Drugs (ADE)**" which is outlined below. Additional study forms and documentation are attached as Appendixes A-F.

I. DESCRIPTION OF SERVICES

A. Background

Adverse events due to therapeutic drugs (ADEs) may be responsible for over 100,000 deaths a year, which would make ADEs the 5th leading cause of death in the United States (JAMA 1998;279:1200-5, 1216-7). Several large studies have focused on ADEs in the hospital setting. In the outpatient setting, however, we know relatively little about adverse drug events.

The National Electronic Injury Surveillance System – All Injury Program (NEISS) can play an important role in collecting information about outpatient ADEs. However, according to a recent audit, NEISS coders were less successful in identifying ADEs than any other cause of injury. According to this audit, only 26.5% of ADEs were correctly identified.

After reviewing details of the cases of ADEs reviewed in the system-wide audit, we believe that supplemental training of NEISS hospital coordinators will significantly improve the identification and reporting of injuries related to ADEs. Based on data from the system-wide audit, a self-guided supplemental training module to improve case ascertainment of ADEs has been developed (Appendix A).

B. Purpose

This study will examine the acceptability, feasibility, and effectiveness of the self-guided supplemental training module designed to improve identification of cases of ADEs. The National Center for Injury Prevention and Control (NCIPC) proposes to fund both a pre-pilot and a pilot study. If the pre-pilot and pilot study of this supplemental training module are successful,

we will recommend the implementation of supplemental training for all NEISS-AIP hospital coordinators and the continued collection of cases of adverse events due to therapeutic drugs.

C. Methods

The pre-pilot study will refine the content and implementation design of the supplemental training module (Appendix A) which is designed to improve case ascertainment of ADEs by NEISS-AIP hospital coordinators. This training module has been developed based on data from the system wide audit of NEISS-AIP conducted by AdvanceMed between January and July 2001.

The pilot study will assess the effectiveness of the self-guided supplemental training in improving case ascertainment of ADEs by NEISS-AIP. Hospital coordinators at half of the hospitals will receive the self-guided supplemental training alone. The other half will receive the self-guided supplemental training and also be asked to fill out an additional one-page form. For each form completed, the hospital coordinators will be paid a nominal amount. In other studies, an additional form and payment have been found to increase reporting of cases and case detail.

Effectiveness will be evaluated by comparison of pre- and post-intervention counts of cases of ADEs in individual pilot study hospitals and comparison of pre- and post-intervention counts of cases of ADEs between pilot study hospitals and non-participating hospitals. Pilot study hospitals which completed the additional one-page forms will be compared to those which received only the supplemental training to determine if the collection of this additional data improves case ascertainment and case detail.

D. Pre-Pilot

1. Sample of hospitals: Four hospitals with scheduled CPSC site visits in the spring of 2002 will be selected for the pre-pilot study. Based on data from July 2000-June 2001, some NEISS-AIP hospitals have higher case ascertainment of ADEs than others. CPSC will recruit two hospitals with higher case ascertainment and two hospitals with lower case ascertainment willing to participate in the pre-pilot.
2. Pre-intervention record review: A researcher from NCIPC will accompany CPSC personnel during the scheduled CPSC site visit of the sample hospital. While the CPSC personnel conduct their customary review of logs and charts, the NCIPC researcher will review the ED logs and charts to document all cases of ADEs during the time period of review using the attached instruments (Appendices B, C). Ideally, copies of selected records, with personal identifiers removed, could be obtained for the purposes of refining the training instrument.
3. Supplemental training: After reviewing ED logs and charts, the NCIPC researcher will give the hospital coordinator the 30 minute self-guided supplemental training module on case ascertainment of ADEs (Appendix A). This supplemental training will then be used by the hospital coordinator for data collection from that date forward. Examples from the pre-

intervention record review may also be used in the supplement training to demonstrate how to use the principles from the supplemental training to find and report ADE cases. The NCIPC researcher will be available for any questions that arose during the site visit. The email address and telephone number of the NCIPC researcher will also be made available to hospital coordinators for any questions regarding ascertainment of ADE cases in subsequent weeks.

4. Post-intervention feedback: Immediately after completing the supplemental training module, the NCIPC researcher will be available to answer any questions relating to the training and to obtain feedback from each hospital coordinator (Appendix D). At the set intervals (1, 3, and 6 weeks after the supplemental training) the NCIPC researcher will contact the hospital coordinators from the hospitals in the pre-pilot for feedback on improving ADE case ascertainment training (Appendix E). Suggestions for improvement will be incorporated into a refined supplemental training module for use in the pilot study.

5. Evaluation of Efficacy: To evaluate the efficacy of the supplemental training module,

NCIPC biostatisticians will request a preliminary dataset from CPSC for these 4 hospitals. This dataset will include all cases with product codes indicating involvement of a medication from 60 days preceding the supplemental training to 60 days following the supplemental training. These cases will be reviewed by the NCIPC researcher and the number and type of ADEs collected before and after the supplemental training will be calculated. Comparing the proportion of ADEs per 100 injury visits in the pre- and post- intervention periods will estimate the efficacy of the supplemental training in improving ADE case ascertainment. Revisions will be made to the supplemental training module and forms prior to beginning the pilot study.

E. Pilot Study

1. Sample of hospitals: CPSC will recruit 10 hospitals, ideally 2 from each hospital strata to participate in the pilot study. By random assignment, 5 of the hospitals will receive supplemental training alone and the other 5 hospitals will receive self-guided supplemental training and also be asked to fill out an additional one-page form. For each form completed, the hospital coordinators will be paid a nominal amount.

2. Supplemental Training: The revised supplemental training module will be mailed to 10 hospital coordinators with instructions to review the materials by a specified date and incorporate the practices taught into data collection. On the date specified for review of the supplemental training module, the CPSC researcher will contact the hospital coordinators by telephone to answer any questions relating to the training. The NCIPC researcher will also be available for any questions that may arise by telephone and email during subsequent weeks.

3. Data Collection Form: The additional one-page data collection forms (Appendix F) will be mailed with the supplemental training module. CPSC will coordinate payment and collection of these forms. Copies of these forms will be provided to the NCIPC researcher.

4. Post-intervention feedback: At certain intervals (1, 3, and 6 weeks after the supplemental training) the NCIPC researcher will contact the NEISS hospital coordinators from the hospitals in the pilot study for feedback on improving ADE case ascertainment methods and training (Appendix E).

5. Evaluation of Effectiveness: For each hospital a preliminary dataset will be requested from CPSC, and the proportion of ADEs per 100 injury visits in the 60 days preceding the supplemental training and the 60 days following the supplemental training will be calculated and compared as described for the pre-pilot. The proportion of ADEs per 100 injury visits in the 60 days preceding the date of the supplemental training and the 60 days following the supplemental training will also be calculated for hospitals that did not participate in the pilot study and compared to the proportions in pilot study hospitals.

The change in the proportion of ADEs per 100 injury visits in the hospitals which completed the additional one-page forms will be compared to those which received only the supplemental training to determine if the collection of this additional data improves case ascertainment. The data on the one-page forms will be compared to the data collected in the narrative comments to determine if the one-page forms provide additional case detail.

II. DURATION OF AGREEMENT

This agreement is approved from the date of signature for both agencies through December 31, 2002.

III. ESTIMATED COSTS

\$36,250.00

IV. FUNDING

All funds provided by CDC in this agreement must be obligated by the performing agency by the end of the fiscal year in which the funds expire. Any unobligated but expired funds may not be used to fund services in subsequent periods. The CDC Financial Management Office (FMO) must be notified of any unobligated funds pertaining to this agreement at least 15 days before the end of the fiscal year so that the agreement can be amended to reduce the obligated amount when appropriate. The notification must be provided to the address cited below (in paragraph V).

V. ACCOUNTING AND BILLING INFORMATION

Funds for this project for FY2000 in the amount not to exceed \$ 36,250.00 will be transferred to CPSC via OPAC using the following account data:

	<u>From</u>	<u>To</u>
Agency	CDC	CPSC
Agency Symbol	75-09-0421	4610000010
Appropriation	7590943	02 PS EXOB 4310 11179 252e
CAN	2921 1985	
Object Class	25.39	
Amount	\$ 36,250.00	\$ 36,250.00
EIN No	58-6051157	52-0978750

When billing CDC through the OPAC system, CPSC will reference agreement number: 00FED05404-01.

When funds are provided to the performing agency in advance of services being performed or goods being delivered, the performing agency is required to provide, within 15 days of the end of each quarter, statements of obligations and expenditures made during the quarter. These statements are also provide to the address below:

CDC, FMO
Attn: OPAC Desk
1600 Clifton Road, MS D-06
Atlanta, GA 30333

VI. EQUIPMENT

There is no equipment to be covered under this agreement.

VII. TRAVEL

No travel costs are associated with this Interagency Agreement.

VIII. CONFLICT WITH EXISTING AGREEMENTS

There is no duplication or conflict with existing agreements, policy, or statute.

IX. PROGRAM CONTACTS

CDC: Dan Budnitz, M.D.
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Atlanta, Georgia 30341-3714
Phone: (770) 488-1486
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CPSC: Art McDonald
CPSC
4330 East West Highway, Rm 604D
Bethesda, MD 20814-4408
Phone: (301) 504-0539, ext.1249
Fax: (301) 504-0038
Email: amcdonal@cpsc.gov

X. BUDGET CONTACTS

CDC: Diana Miles
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CPSC: Donna Hutton
Contracting Officer, CPSC
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Phone: (301) 504-0444, ext.1421
Fax: (301) 504-0038
Email: DHutton@cpsc.gov

XI. MODIFICATION AND CANCELLATION

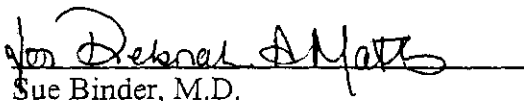
This agreement may be modified by mutual consent of both parties or canceled upon 60 days advance written notice by either party.

XII. AUTHORITY

This agreement is entered into under Section 601 of the Economy Act, as amended (31 U.S.C. 1535) and the Consumer Product Safety Act.

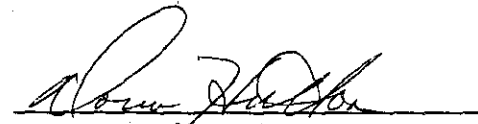
XIII. APPROVALS

For NCIPC:


Sue Binder, M.D.
Director, National Center for Injury
Prevention and Control

Date: 5/20/02

For CPSC:


Donna Hutton
Contracting Officer
U.S. Consumer Product Safety
Commission

Date: 6/11/02

Appendix A.

Supplemental Training Module (For pre-pilot training of NEISS-AIP hospital coordinators)

SUPPLEMENTAL TRAINING MODULE FOR NEISS-AIP HOSPITAL CODERS:

Tips for Finding Adverse Drug Events (ADEs)

Any Questions?

Contact:

Dan Budnitz

National Center for Injury Prevention and Control

Centers for Disease Control and Prevention

dbudnitz@cdc.gov

770-488-1486

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I. The Importance of Adverse Drug Events (ADEs)

Adverse Drug Events (ADEs) may be responsible for over 100,000 deaths a year, which would make ADEs the 5th leading cause of death in the United States (JAMA 1998;279:1200-5, 1216-7). Several large studies have focused on ADEs in the hospital setting; however, we know little about adverse drug events that happen outside the hospital. In addition, NEISS can collect information on ADEs due to over-the-counter medications and nutritional supplements.

NEISS hospital coordinators play a crucial role in collecting information on ADEs. Detecting cases of ADEs can be more difficult than finding the typical injury cases reported in NEISS, however. This supplemental training module has been designed to make finding and reporting cases of ADEs faster and easier.

The information on ADEs collected by NEISS coordinators could lead to improvements in drug safety for thousands or even millions of Americans each year.

II. Finding Adverse Drug Events – Three Simple Tips

Detecting cases of ADEs is different than finding typical injury cases because the adverse effects of drugs often look like the symptoms of other injuries or illnesses. However, using these 3 tips, you will be able to find almost all ADEs.

The Three Tips

Review *Every Entry* in the Diagnosis / Impression Section of the chart

- 1. Look for *Key Words* that link a drug to an injury**
- 3. Look carefully at *Certain Symptoms* which may be linked to drugs**

1. Review Every Entry in the Diagnosis/Impression Section of the chart

Often you cannot tell if an injury is due to an ADE by looking at the ED log or the primary diagnosis.

For each chart look at all the diagnoses and impressions

Example: "59 yo F with sick stomach x 3 wks, decreased appetite, occasional chest pain. Dx: Digoxin toxicity"

Explanation: If we look only at the ED log or the chief complaint of "sick stomach," we would miss this ADE. By checking the diagnosis section (Dx), we find that the "sick stomach" was an adverse effect of a drug the patient was taking, Digoxin

Example: "60 yo F w/ 3 days of numerous bloody bowel movements. Feels weak. Dx: GI bleed; likely upper; probably related to NSAID use"

Explanation: If we look only at the first part of the diagnosis section, we would see only "GI bleed" and miss the ADE. By checking every entry in the diagnosis section, we find that the "GI bleed" was probably an adverse effect of a drug the patient was taking, in this case a NSAID.

2. Look for **Key Words** (and their abbreviations) that link a drug to an injury

Many ADEs can be easily identified by looking for the following key words linked to a medication:

- **Adverse Reaction** (Adv Rxn)
- **Allergic Reaction** (All Rxn)
- **Anaphylactic Reaction** (Anaphylaxis)
- **Reaction** (Rxn)
- **Side-Effect** (S/E, s/e)
- **Toxicity** (tox, excess, overdose, OD)
- **Secondary to** (2nd to, due to, related to, induced by)
- **Sensitivity to** (hypersensitivity to)
- **Accidentally took**

Example: "Patient had reaction to meds"

Explanation: Some charts have very little documentation, but the key word reaction is associated with a drug (in this case the specific medication is missing) so this entry should be collected.

Example: "86 F here yesterday w/seizures. Has redness all over, agitated. Dx. Acute allergic rxn to Dilantin; acute agitation"

Explanation: Again, if we look only at the chief complaint of "redness all over" we would miss the ADE. The diagnosis section tells us that the cause of the redness was an allergic reaction to a drug, Dilantin.

Example: "10 month male with several bouts of emesis today. Finished taking amoxicillin. Now taking erythromycin for ear infection. Dx: emesis – prob 2nd to erythromycin"

Explanation: Patient has a symptom secondary to a drug, (erythromycin)

Example: "47 yo F w/side effect to Effexor. Lightheadedness and drugged feeling"

Explanation: Patient has a side-effect of a medication, Effexor

2. Look carefully at Certain Symptoms which may be linked to drugs

The following symptoms are typical of ADEs and if you see one of these symptoms, look carefully to see if a medication causes the symptom.

- **Bleeding** (epistaxis)
- **Urticaria** (hives)
- **Nausea & vomiting** (N&V, emesis)
- **Rash** (dermatitis)

Example: "51 y/o BF w/ bloody stool in pt w/ IBD on coumadin. Lower GI bleed vs IBD. Dr states that patient should not be on coumadin."

Explanation: Patient has a symptom (bleeding) likely related to the effect of a drug (coumadin)

Example: "16 mo M developed diarrhea after 1 day PO amoxicillin. Dx: antibiotic induced diarrhea."

Explanation: Patient has a symptom (diarrhea) likely related to the effect of a drug (amoxicillin)

II. Reporting Adverse Drug Events

1. When should I report a case that looks like an ADE?

Report **all cases** where a patient sustained an **injury** that is **linked to a drug**

Recall that an injury is: "A medical condition resulting from contact with external forces or energy." Forces can be mechanical, chemical, thermal, electric, or radioactive. Drugs usually cause harmful medical conditions by chemical energy.

Example: "Rash on back and chest after taking amoxicillin"

Example: "Abdominal pain, nausea and vomiting secondary to taking erythromycin"

Example: "Lower GI bleeding attributed to a high INR in a patient taking coumadin"

Drugs are not just prescription medications, they include:

- **Prescription medications** (antibiotics, anti-depressants, narcotics)
- **Over-the-counter medications** (pain-relievers, cold medications, antacids)
- **Topical medications** (creams, ointments)
- **Other medications** (vaccinations, vitamins)
- **Nutritional supplements** (Creatine, St. John's Wort)
- **Illegal substances** (crack, heroine, methamphetamine)

Example: "Allergic reaction to Neosporin used on burn to hand"

Example: "Child ingested 10-20 children's vitamins with iron. Dx: iron overdose"

Example: "Male found at local party with decreased level of consciousness, +EtOH, marijuana, and Lortab"

2. When should I **NOT** report a case which has a drug mentioned?

- If the medication listed is *not related* to the reason the patient came to the emergency department, do NOT report
- If the medication causing the injury was given *during the visit* to the emergency department, do NOT report
- The medication listed was used to *treat* an injury, do NOT report

Example: "Patient had swelling of face after bee-sting. Patient took EpiPen before arriving to hospital."

Explanation: The injury (swelling) was due to the bee-sting. The drug (EpiPen) was used to treat the injury

IV. Narrative Comments for Adverse Drug Events

What information should go in the narrative of an ADE?

Include as much detail as possible about the drug, circumstances, injury, and treatment

After an injury case attributed to a drug is reported to CPSC, coders at CPSC determine if the injury is an ADE or a poisoning. To make this distinction, the CPSC coders consider drug type, dosage, delivery mechanism, intent, type of injury, and other factors. Therefore, it is important to record as much information as possible about the circumstances of the injury in the narrative comments.

If any of the following information is available, record:

- **Name of drug** (the most specific name reported)
- **Dosage of drug** (number of pills taken, time period in which taken, milligrams in each tablet)
- **How delivered** (swallowed ointment, pill stuck in throat)
- **Intent of patient** (drug taken in suicide attempt, taking another person's drug, child accidentally took)

- **Injury type** (swelling of a body part, rash over a body part, blood per rectum)
- **Lab tests**, if available (INR/PT, digoxin level, phenytoin level)
- **Treatment** (activated charcoal, observation, gastric lavage)

IV. FAQs (Frequently Asked Questions)

1. What if the ED clinician writes that an event or symptom is “probably” related to a drug?

DO report the event if the clinician uses the following words (or abbreviations) to describe the cause:

- Probable (prob.)
- Likely

Do NOT report the event if these words (or abbreviations) are used to describe the cause:

- Doubt
- Unlikely (not likely)

If you are uncertain, do report the case and record the exact wording used in the medical record in the narrative comments

3. What if it is not known if a patient, for example a child, actually took the drug or not?

If the patient was treated for a drug reaction or diagnosed with a drug reaction do report the event. In these cases especially, try to report as much detail as possible about the circumstances in the narrative comments.

4. What if I am not sure if a word written in the chart is a medication or not?

In addition to bad penmanship, clinicians may also misspell medication names or use non-standard abbreviations. If it the injury might be linked to a drug, report it. As always, record the word exactly as it is spelled in the medical record.

5. What if the drug’s name is not written in the ED chart?

Whenever possible, the drug name should be included in the narrative that is entered. If no specific drug is mentioned, still enter as much detail as possible in the narrative.

6. What if an illegal drug, like crack cocaine or ecstasy causes an adverse event?

These events should be recorded. Coders at CPSC may classify the external cause of these events as poisonings, but they should certainly be reported.

7. What if an over-the-counter medication causes an adverse event?

All medications, including over-the-counter medications can cause ADEs and should be reported. Also report vitamins, nutritional supplements, diet aids, and herbs that cause adverse events.

8. What if a patient takes a medication in greater dosage than prescribed?

All these cases should be recorded. At CPSC these may be classified as poisonings or ADEs depending on the additional information collected in the narrative.

9. What if a drug given in the emergency department causes an ADE?

If a patient has an adverse event related to a drug given while the patient is receiving emergency care in the ED, you should not report this event. NEISS-AIP is designed to detect injuries that occur before the patient come to the ED

10. What if I have a question about reporting a case?

During this pilot study please feel free to call Dr. Dan Budnitz in the National Center for Injury Prevention and Control, CDC. He can be reached Monday – Friday from 9am – 5pm EST at 770-488-1486. He can also be reached by email at dbudnitz@cdc.gov.

Appendix B.
Draft ED log review instrument
(For use by NCIPC researcher)

Hospital Name:

ID#:

Date:

Time Period of Review

Beginning - Date: Time:

Ending - Date: Time:

Total ED visits:

Total ED charts available:

Total ED charts reviewed:

Total NEISS-eligible injury visits:

Appendix C.
Draft ED record review instrument (for use by NCIPC researcher)

Patient Name:

MR#:

Date of Visit:

Time of Visit:

Narrative describing Adverse Event – Therapeutic Drugs (ADE):

Source of Narrative:

Patient Name:

MR#:

Date of Visit:

Time of Visit:

Narrative describing Adverse Event – Therapeutic Drugs (ADE):

Source of Narrative:

Patient Name:

MR#:

Date of Visit:

Time of Visit:

Narrative describing Adverse Event – Therapeutic Drugs (ADE):

Source of Narrative:

Appendix D.

Draft Immediate feedback form

(For use by NEISS-AIP hospital coordinators immediately after completing supplemental training)

What information in the supplemental training module on adverse drug events did you find most helpful?

Did you find any part of the training module confusing?
If so, which part(s)?

Is there any additional information you would find helpful?

Was this training module too short, too long, or about the right length?

Do you have any suggestions for improving the training module?

Appendix E.
Draft Post-intervention feedback form
(For use by NEISS-AIP hospital coordinators week 1, 3, and 6 after implementing supplemental training)

How many weeks has it been since you completed supplemental training on improving ascertainment of cases of adverse effects – therapeutic drugs (ADEs)?

1 week

3 weeks

6 weeks

Has the supplemental training increased the number of cases of ADEs you have entered into NEISS?

Yes

No

Approximately how many ADE cases did you find per week before the intervention?

Approximately how many ADE cases did you find per week after the intervention?

If the supplemental training has helped you find ADE cases, describe 3 examples of how it has helped:

1.

2.

3.

If the supplemental training has not helped you find ADE cases, describe the reasons why it has not helped:

1.

2.

3.

Appendix F.
Draft One-Page Form

ADE Pilot Study "Second Screen"

Hospital Name: _____

Treatment Date: _____

Coder Initials _____

Case No. _____

1. Where in the medical record did it indicate the presence of an adverse event related to a medication?
(Examples: *Logbook, Chief Complaint, History and Physical, Assessment*) Indicate all that apply.

2. How was the medication taken? (Examples: *Orally, Inhaled, Skin contact, Eye contact, Rectally*)

3. What was the name of the medication? _____

4. What was the dose of the medication? _____
(Copy exactly as written in the chart)

5. Describe the circumstances of the event? _____

7. What was the injury? _____

8. What was the treatment? _____

9. Was poison control called before
the patient came to the ED? Y N not stated

10. Was a health provider contacted
before coming to the ED? Y N not stated